

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

**NOVAPLAST CORPORATION,**

**Plaintiff,**

**v.**

**INPLANT, LLC and PROXIMATE  
CONCEPTS, LLC,**

**Defendants.**

Civ. No. 20-7396 (KM) (JBC)

**OPINION & ORDER**

**KEVIN MCNULTY, U.S.D.J.:**

This patent infringement case is brought by NovaPlast Corporation (“NovaPlast”) against Inplant, LLC (“Inplant”) and Proximate Concepts, LLC (“Proximate”). The patent-in-suit is U.S. Patent No. 10,105,213 (the “’213 Patent”). This patent claims a funnel-like device to assist in the implantation of a prosthetic, such as a breast implant. Much of the dispute centers around the extent to which certain patent claims encompass a single-first-fastener device, a multiple-first-fastener device permitting the user to adjust the size of the distal opening, or both.

NovaPlast commenced this infringement action asserting claims under federal law for direct patent infringement, indirect patent infringement, and willful patent infringement under 35 U.S.C. § 271 *et seq.* This Opinion contains the Court’s construction of key patent terms following a *Markman* hearing.<sup>1</sup>

**I. BACKGROUND**

**A. The ’213 Patent**

By way of assignment, NovaPlast is the current owner of the ’213 Patent, entitled “Prosthetic implant delivery device and method.” (See Baton Decl. Ex.

---

<sup>1</sup> The reference is to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

1.)<sup>2</sup> The claimed invention consists of “a delivery apparatus for facilitating the insertion of a prosthesis, such as a breast implant, into a surgical pocket.” (*Id.* col. 1:6–8.) NovaPlast claims infringement of ’213 Patent claims 1 and 5:

1. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:

a flexible elongated member defining a proximal end and a distal end, the proximal end formed opposite the distal end and defining a closed end, the distal end defining a longitudinal opening;

the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening, at least one first fastener formed on the elongated member adjacent the first longitudinal edge, and a second fastener formed on the elongated member adjacent the second longitudinal edge;

the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening, whereby a predetermined size distal opening is formed

---

<sup>2</sup> Certain key items from the record will be abbreviated as follows:

“DE” = Docket entry number in this case

“Joint Statement” = Joint Claim Construction and Prehearing Statement (DE 55)

“Pl. Br.” = NovaPlast’s Opening Claim Construction Brief (DE 56)

“Baton Decl.” = Declaration of William C. Baton in Support of NovaPlast’s Opening Claim Construction Brief (DE 56-1)

“Def. Br.” = Inplant and Proximate’s Opening Claim Construction Brief (DE 57)

“Gabathuler Decl.” = Declaration of Henry A. Gabathuler in Support of Defendants’ Opening Claim Construction Brief (DE 57-1)

“Def. Resp.” = Inplant and Proximate’s Responsive Claim Construction Brief (DE 59)

“Pl. Resp.” = NovaPlast’s Responsive Claim Construction Brief (DE 60)

“Baton Resp. Decl.” = Declaration of William C. Baton in Support of NovaPlast’s Responsive Claim Construction Brief (DE 60-1)

based on the engagement of the second fastener with the at least one first fastener, the distal opening sized to allow the prosthetic implant to be urged therethrough.

. . .

5. The delivery system of claim 1, each of the at least one first fastener further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of the first fasteners.

(Baton Decl. Ex. 1, col. 8:13–33, 8:42–46 (corrections from Certificate of Correction included, Ex. 1 p. 16)).<sup>3</sup>

### **B. Patent Prosecution History**

On December 29, 2015, patent application serial number 14/982,250, identifying Jeffrey Weinzweig as the sole inventor, was filed (the “’250 Application”).<sup>4</sup> (Gabathuler Decl. Ex. B.) Claim 8 of the ’250 Application, which became claim 1 of the ’213 Patent, originally claimed a “plurality” of first fasteners:

8. A delivery system adapted to facilitate insertion of a prosthetic implant through a surgical opening, the system comprising:

a flexible elongated member defining a proximal end and a distal end; at least the distal end defining a longitudinal opening;

the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening,

---

<sup>3</sup> A word about terminology, setting aside construction of claims. “First fastener” refers to a fastener on one side of the distal opening. Definitionally, there could be more than one “first fastener” on the same side of the longitudinal opening. The term “second fastener” is reserved for a fastener on the other side of the longitudinal opening.

<sup>4</sup> The ’250 Application initially contained 18 claims, but claims 16, 17, and 18 were withdrawn. (Gabathuler Decl. Ex. C.)

*a plurality of first fasteners formed on the elongated member adjacent the first longitudinal edge, and a second fastener formed on the elongated member adjacent the second longitudinal edge;*

*the second fastener adapted to engage with at least one of the first fasteners and to close the longitudinal opening, whereby a predetermined size distal opening is formed based on the selected engagement of the second fastener with one of the first fasteners.*

(Gabathuler Decl. Ex. B (emphasis added).) Claim 1 of the '250 Application described a similar delivery system with a plurality of first fasteners. (*See id.*)

On January 12, 2018, the United States Patent and Trademark Office ("USPTO") issued a non-final action rejecting the 15 claims of the '250 Application as anticipated by or unpatentable over prior art. Specifically, the USPTO examiner considered prior art Guetty, U.S. Publication 2007/0038310 ("Guetty"); Preissman, U.S. Publication 2010/0280610 ("Preissman"); DiPoto et al., U.S. Publication 2003/0153927 ("DiPoto"); and Schmitt et al., U.S. Patent 3,463,158. (Gabathuler Decl. Ex. C.) Regarding claims 1 and 8, the examiner determined that Guetty similarly disclosed a plurality of first fasteners and that the first and second fasteners matingly engaged, "whereby a predetermined size distal opening is formed based on the selected engagement of the second fastener with one of the first fasteners." (*Id.* pp. 3–4.) The examiner also distinguished Preissman from the present invention:

However, Preissman does not expressly disclose a plurality of first fasteners formed with the first side portion, each of the first fasteners disposed in a generally longitudinal relationship with the first edge; and a second fastener formed with the second side portion and disposed in a generally longitudinal relationship with the second edge, the second fastener adapted to matingly engage with at least one of the first fasteners and to secure the first side portion with the second side portion, whereby a predetermined size distal opening is formed based on the selected engagement of the second fastener with one of the first fasteners.

(*Id.* p. 6.) Instead, Preissman disclosed a first side portion comprising an adhesive that mates with the second side portion to form a seal. (*Id.*)

NovaPlast<sup>5</sup> responded to that initial Patent Office action on April 10, 2018. (Gabathuler Decl. Ex. G.) That response amended claims 1 and 8 to include the phrase “the distal opening sized to allow the prosthetic implant to be urged therethrough”:

1. . . . the second fastener adapted to matingly engage with at least one of the first fasteners and to secure the first side portion with the second side portion, whereby a predetermined size distal opening is formed based on the selected engagement of the second fastener with one of the first fasteners, the distal opening sized to allow the prosthetic implant to be urged therethrough.

8. . . . the second fastener adapted to matingly engage with at least one of the first fasteners and to close the longitudinal opening, whereby a predetermined size distal opening is formed based on the selected engagement of the second fastener with one of the first fasteners, the distal opening sized to allow the prosthetic implant to be urged therethrough.

(Gabathuler Decl. Ex. G pp. 2–3).<sup>6</sup> NovaPlast gave several reasons for disputing the examiner’s determination that claims 1 and 8 were anticipated by Guetty. Most relevant to the present discussion is NovaPlast’s assertion that Guetty did not disclose first or second fasteners *at all*:

Guetty merely discloses a string that is used to fasten two sides of a sheet together. Absent the string, the sides of the Guetty sheet could not be fastened to one another. As such, there is no disclosure of first and second fasteners that are matingly engageable with one another as is claimed.

(*Id.* p. 7.) In the alternative, NovaPlast argued that Guetty did not disclose a *plurality* of first fasteners: “Even if one could contend that one longitudinal portion of Guetty is a first fastener, there is no teaching of a plurality of first

---

<sup>5</sup> Although NovaPlast is not the applicant, the parties do not raise any dispute regarding whether the statements made during the prosecution history are attributable to NovaPlast. It also appears from the amended complaint that Jeffrey Weinzwieg is affiliated with NovaPlast. (See DE 29 ¶ 55.) Therefore, for consistency in this Opinion, I will refer to the applicant as NovaPlast.

<sup>6</sup> As presented to the examiner; underlined text shows the addition of words.

fasteners as is claimed.” (*Id.*) NovaPlast also distinguished its invention from DiPoto, asserting that DiPoto does not disclose a plurality of first fasteners: “With respect to claims 1 and 8, the claims require a plurality of first fasteners. This is not disclosed in DiPoto. The examiner cites a rivet/screw as the first fastener. Even if one assumes this is correct, there is not a plurality of first fasteners disclosed.” (*Id.* p. 9.)

The USPTO filed its response on July 13, 2018, in which it rejected all 15 claims. (Gabathuler Decl. Ex. H.) The examiner, disagreeing with NovaPlast, determined that Guetty does disclose first and second fasteners—the first fasteners in the form of receiving slots and the corresponding second fastener in the form of a locking member that mates with the receiving slots. (*Id.* p. 2.) The examiner also determined that Guetty and DiPoto disclose a plurality of first fasteners. (*Id.* p. 3.) The examiner continued to distinguish Preissman for the same reasons stated in the prior decision, *supra*. (*Id.* p. 8.)

On July 25, 2018, the USPTO convened an applicant-initiated interview, wherein the USPTO and NovaPlast discussed amendments to claims 8 and 9 aimed at overcoming the current rejection over Guetty:

Applicant proposed adding the limitation [that] the elongated member includes a proximal and distal end, wherein the proximal end is entirely closed therefore the prosthesis has exactly one opening to overcome the current 102 rejection over Guetty. . . . Applicant proposed amending claim 8 to further include the limitations of claim 9 to further define the proximal end disposed opposite to the distal end and the proximal end is closed to form a prosthesis with exactly one opening at the distal end. . . . The examiner agreed that having only a single opening at a distal end and having a proximal end that is completely sealed/closed would seemingly overcome the current 102 rejection over Guetty.

(Gabathuler Decl. Ex. I.)

On July 30, 2018, NovaPlast filed its amendments. (Gabathuler Decl. Ex. J.) NovaPlast cancelled claims 1 through 7 of the '250 Application, without prejudice, and amended claim 8 to include “the proximal end formed opposite the distal end and defining a closed end,” as discussed with the examiner. (*Id.*

p. 2.) NovaPlast also amended claim 8 to change any reference to a “plurality of first fasteners” to “at least one first fastener”:

8. . . . the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening, ~~a plurality of first fasteners~~ at least one first fastener formed on the elongated member adjacent the first longitudinal edge, and a second fastener formed on the elongated member adjacent the second longitudinal edge;

the second fastener adapted to matingly engage with the at least ~~one of the first fastener fasteners~~ and to close the longitudinal opening, whereby a predetermined size distal opening is formed based on the ~~selected~~ engagement of the second fastener with the at least one first fastener ~~one of the first fasteners~~, the distal opening sized to allow the prosthetic implant to be urged therethrough.

(*Id.* pp. 2–3.)<sup>7</sup> References in claims 12, 13, 14, and 15 to a “plurality of first fasteners” were likewise removed and replaced with “at least one first fastener.”

(*Id.* p. 3.) NovaPlast explained in its remarks to the examiner that the amendments were to “specify that the proximal end of the delivery system is a closed end” and, therefore, distinguishable from Guetty. (*Id.* p. 4.)

On September 4, 2018, the USPTO allowed claims 8 through 15 and the examiner provided a statement of reasons for the allowance. (Baton Resp. Decl. Ex. 3.) The examiner determined that the closest prior art was Preissman. (*Id.*) In the examiner’s view, the present invention was distinguishable from Preissman because “Preissman does not expressly disclose nor render obvious the first longitudinal edge and the second longitudinal edge defining the longitudinal opening and a first fastener formed on the first longitudinal edge and a second fastener formed on the second longitudinal edge, wherein the second fastener matingly engage with the first fastener to close the longitudinal opening.” (*Id.* pp. 2–3.)

---

<sup>7</sup> As presented to the examiner; underlined text shows the addition of words and strikethrough text shows the deletion of words.

### C. Procedural History

The Court held a *Markman* hearing on April 11, 2023. (DE 69.) Prior to the hearing, the parties submitted opening briefs, as well as briefs in response. (DE 55, 56, 57, 59, 60.) Defendant also submitted supplemental authority, to which NovaPlast replied. (DE 68, 70.) I am now prepared to rule on the meaning of the disputed claim terms.

### II. LEGAL STANDARD

A patent infringement case involves two steps. First, the court determines the meaning of the claims in the patent. *Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368, 1375 (Fed. Cir. 2020). Second, the court compares the claims, as construed, to the allegedly infringing product. *Id.*

We are now concerned with the first step, known as claim construction. Where, as here, the parties dispute the meaning of the patent's claims, resolution of those disputes is an issue for the court. *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 977 (Fed. Cir. 2021). This task primarily requires construal of written documents (quintessentially, the patent itself), but some factual determinations may be needed to assist in understanding the written words. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–26 (2015). Accordingly, there is a hierarchy of sources to be considered when construing a claim, arranged in decreasing order of importance. *Profectus Tech. LLC v. Huawei Techs. Co.*, 823 F.3d 1375, 1380–81 (Fed. Cir. 2016).

Of course, I “begin with the words of the claims themselves.” *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1373 (Fed. Cir. 2019) (citation omitted). Those words receive the meaning that “a person of ordinary skill in the art” (“POSA”) would give them. *Id.* (citation omitted). A POSA would interpret the words in the context of the rest of the patent document, including the specification which describes the invention. *Id.* at 1373 & n.6. The prosecution history, *i.e.*, proceedings before the USPTO that led to approval of the patent, can further illuminate the meaning of a term. *Id.* at 1373 & n.7. All



of the foregoing constitutes “intrinsic evidence,” *i.e.*, evidence from within the patent process itself.

I may also turn to “extrinsic evidence,” or evidence outside the patent and prosecution history. *Id.* at 1373 & n.8. Such extrinsic evidence includes “expert and inventor testimony, dictionaries, and learned treatises.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). In general, however, extrinsic evidence is less reliable than the patent and prosecution history. *Id.* at 1318. For that reason, extrinsic evidence is second-priority, and cannot “trump the persuasive intrinsic evidence.” *Immunex Corp. v. Sanofi-Aventis U.S. LLC*, 977 F.3d 1212, 1221–22 (Fed. Cir. 2020) (citation omitted).

### **III. DISCUSSION**

Defendants, Inplant and Proximate, seek construction of five claim terms. Three of the claim terms regard the number of “first fasteners” present in the claimed device: (1) “at least one first fastener”; (2) “each of the at least one first fastener”; and (3) “the first fasteners.” Inplant and Proximate also seek construction of the claim term “based on the engagement of the second fastener with the at least one first fastener” to define the role that engagement of the fasteners may play in forming “a predetermined size distal opening.” Finally, Inplant and Proximate seek construction of the claim term “formed on the elongated member” to define the manner in which a fastener is provided on the elongated member.

NovaPlast contends that no construction is necessary, in that the plain meaning of the claim language should control.

I discuss each of the disputed claim terms in turn.

#### **A. Claim 1 “at least one first fastener”**

This district’s local patent rules require the parties to present patent construction issues jointly, in summary chart form. As to this term, the parties present the dispute as follows:

<b>Term</b>	<b>Plaintiff's Construction</b>	<b>Defendants' Construction</b>
“at least one first fastener”  (’213 Patent, cl. 1)	No construction is necessary such that the plain and ordinary would apply, e.g., one or more securable elements.	At least one among more than one first fastener, which are spaced apart.

In the relevant claim, claim 1, the term “at least one first fastener” appears twice:

the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening, *at least one first fastener* formed on the elongated member adjacent the first longitudinal edge, and a second fastener formed on the elongated member adjacent the second longitudinal edge;

the second fastener adapted to matingly engage with the at least first fastener and to close the longitudinal opening, whereby a predetermined size distal opening is formed based on the engagement of the second fastener with the *at least one first fastener*, the distal opening sized to allow the prosthetic implant to be urged therethrough.

(Baton Decl. Ex. 1, col. 8:20–33 (emphasis added).) NovaPlast contends that “at least one first fastener” requires no construction, in that the plain and ordinary meaning of “at least one” is “one or more”. (Joint Statement Ex. A; Pl. Br. p. 7; Pl. Resp. p. 4.)

Federal Circuit precedent suggests that the plain and ordinary meaning of the term “at least one” means that “there could be only one or more than one.” *See Rhine v. Casio, Inc.*, 183 F.3d 1342, 1346 (Fed. Cir. 1999) (“Use of the phrase ‘at least one’ means that there could be only one or more than one.”) (citing *Kistler Instrumente AG v. United States*, 628 F.2d 1303, 1318 (Ct. Cl. 1980) (“Anyone with even the most rudimentary understanding of the English language understands ‘at least one . . .’ to mean ‘one or more . . .’”)).

That plain-language argument is highly persuasive. The phrase “at least one first fastener” in claim 1 has the plain and ordinary meaning of “one or more first fastener(s)”.<sup>8</sup>

Inplant and Proximate offer countervailing arguments. They contend that, despite the plain language, the specification and the prosecution history require that this phrase be interpreted as requiring more than one first fasteners, spaced apart. (Def. Br. pp. 18–19.)

Generally, “claim terms must be construed in light of the specification and prosecution history, and cannot be considered in isolation.” *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1308–09 (Fed. Cir. 2014). However, “the specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal.” *Id.* at 1309. “The standards for finding lexicography and disavowal are exacting. To act as its own lexicographer, a patentee must ‘clearly set forth a definition of the disputed claim term,’ and ‘clearly express an intent to define the term.’ Similarly, disavowal requires that ‘the specification [or prosecution history] make[] clear that the invention does not include a particular feature.’” *Id.* (alterations in original) (quoting *SciMed Life Sys. Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) and citing *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

For the reasons discussed below, I conclude that neither the specification nor the prosecution history provides a basis to displace the plain meaning of this disputed phrase.

---

<sup>8</sup> I have resorted to the ungainly “\_\_\_\_(s)” to signify inclusion of both the singular and plural, because there is no graceful inclusive singular/plural construction in English. The inclusive singular/plural must often be inferred from the context, but, as in this case, is often clear. *Cf. IBSA Institut Biochimique, S.A. v. Teva Pharms. USA, Inc.*, No. 18-cv-00555, 2019 WL 3936656, at \*3 (D. Del. Aug. 20, 2019) (Andrews, J.), *aff’d*, 966 F.3d 1374 (Fed. Cir. 2020) (“[W]hen driving through Montana, I have seen signs saying, ‘Beware of rattlesnakes.’ . . . When I saw this, I understood that a single rattlesnake was something to be wary of.”).

### 1. Disclosed embodiments in the specification

Inplant and Proximate point out that all disclosed embodiments in the specification have a plurality of first fasteners and there is no disclosed embodiment with a single first fastener.<sup>9</sup> (Def. Br. pp. 20–21.) An instructive comparison, say Inplant and Proximate, is provided by the disclosed embodiments with respect to the second fastener, which do clearly indicate one or multiple second fasteners. (*Id.* p. 20.) Because all disclosed embodiments have a plurality of first fasteners, defendants assert that NovaPlast’s interpretation is overly broad. (*Id.* pp. 26–27.)

It is true that the particular embodiments in the specification have a plurality of first fasteners, but that circumstance does not constitute a disclaimer of all single-first-fastener embodiments. The patent does not anywhere state that the applicant disavows or disclaims the plain meaning of “at least one” or seeks to limit the claim to the scope of the disclosed embodiments. Absent such an explicit statement, “it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims.” *See Liebel-Flarsheim Co. v.*

---

<sup>9</sup> The ‘213 Patent describes “some embodiments” of the “present invention” as comprising

a flexible sheet of material defining a first side portion and a second side portion. Formed with either the first side portion or the second side portion, or both of the first and the second side portions are *a plurality of fasteners*. The fasteners are adapted to secure the first side portion with the second side portion to form an elongated hollow form that defines a distal opening. *In that there are a plurality of fasteners, a surgeon can select desired fasteners so that a desired size of the distal opening is determined by way of the particular fasteners that are used.* For example, fasteners towards the edges of the first and second side portions will, when the first and second side portions are secured with one another, define a relatively large distal opening. By contrast, fasteners spaced from the edge of the first or second side portions will, when the first and second side portions are secured with one another, define a smaller distal opening.

(Baton Decl. Ex. 1, col. 2:19–36 (emphasis added).)

*Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004); *contrast Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1321 (Fed. Cir. 2011) (limiting the term “document” to information derived from a hard copy document where the specification explicitly defined the invention as using hard copy documents throughout, such as “*the instant invention provides an integrated and comprehensive system for handling information from a hard copy document*” (emphasis added)).

Finding no actual disavowal or disclaimer in connection with the disclosed embodiments, I cannot accept their particular features as representing a narrowing of the plain-language meaning of “at least one first fastener.”

## **2. Prosecution History**

Inplant and Proximate next argue that, despite the plain language of claim 1, the prosecution history requires a plurality of first fasteners and rules out a single-first-fastener configuration. They point out that from the initial filing of the application and throughout most of the prosecution history, the claims explicitly required a “plurality of fasteners.” Indeed, they say, NovaPlast used that plurality requirement in the application process to distinguish its invention from prior art. (Def. Br. pp. 24–26.) Therefore, according to defendants, the claimed invention must be limited to a plurality of first fasteners, *i.e.*, two or more first fasteners, spaced apart. (*Id.* p. 24.)

I briefly recount relevant portions of the prosecution history, which is described more fully above. In response to the USPTO’s non-final rejection action on January 12, 2018, NovaPlast attempted to distinguish its invention from Guetty and DiPoto. NovaPlast asserted that there was no anticipation of its claims because “Guetty fails to disclose a plurality of first fasteners. Even if one could contend that one longitudinal portion of Guetty is a first fastener, there is no teaching of a plurality of first fasteners as is claimed.” (Gabathuler Decl. Ex. G p. 7.) On similar grounds, NovaPlast distinguished the present invention from DiPoto: “With respect to claims 1 and 8, the claims require a

plurality of first fasteners. This is not disclosed in DiPoto.” (*Id.* p. 9.) In response, the USPTO examiner determined that Guetty and DiPoto disclosed a plurality of first fasteners and initially rejected NovaPlast’s claims. (Gabathuler Decl. Ex. H p. 3.)

During a meeting with the USPTO on July 25, 2018, NovaPlast offered to amend its application to have an entirely closed proximal end. (Gabathuler Decl. Ex. I.) The examiner agreed that closing the proximal end would seemingly overcome the current rejection over Guetty, but that additional time and consideration would be needed. (*Id.*) On July 30, 2018, NovaPlast submitted amendments which added the closed proximal end; removed the multiple first fastener language; and cancelled claims 1 through 7. (Gabathuler Decl. Ex. J.) The examiner reviewed the amended claims and considered the claims in view of Preissman which, unlike Guetty and DiPoto, does not disclose a plurality of first fasteners. (See Baton Resp. Decl. Ex. 3; Gabathuler Decl. Ex. C p. 4, 6; Gabathuler Decl. Ex. H p. 3, 8.) Seemingly the closed proximal end sufficed to distinguish Guetty and DiPoto in the mind of the examiner. In the context of Preissman, which the examiner now considered the “closest prior art,” the invention was found distinguishable because Preissman “does not expressly disclose nor render obvious the first longitudinal edge and the second longitudinal edge defining the longitudinal opening and *a first fastener* formed on the first longitudinal edge and a second fastener formed on the second longitudinal edge, wherein the second fastener matingly engage with *the first fastener* to close the longitudinal opening.” (Baton Resp. Decl. Ex. 3 pp. 2–3 (emphasis added).)

To be sure, the claims evolved in the course of the application process. Inplant and Proximate are claiming, in effect, that NovaPlast, having surmounted the Guetty and DiPoto prior-art objections, inconsistently reinserted the objectionable material late in the process and slipped it past the examiner. I conclude, however, that NovaPlast clearly presented its

amendments to claim 8 and that the final version was not inconsistent with the earlier prior-art rejection.

NovaPlast’s literal interpretation of “at least one first fastener” is not inconsistent with its rejected claims and prior unsuccessful attempts to distinguish prior art related to those claims. (*Contra* Def. Br. p. 34 (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 33 (1966) (“Claims as allowed must be read and interpreted with reference to rejected ones and to the state of the prior art.”)).) To be sure, there was considerable back-and-forth on the issue of multiple and single first fasteners. But in contrast with *Graham*, on which defendants rely, the record does not squarely demonstrate that, in the end, NovaPlast limited the claim to multiple first fasteners and thereby secured approval of the application.<sup>10</sup> See *Graham*, 383 U.S. at 34. What differed in the final form of the application was not the single/multiple fastener but the closed proximal end.<sup>11</sup> The examiner’s final approval did not discuss the Guetty invention, which “could be closed at one of its ends, more preferably at its proximal end.” (See Def. Br. pp. 33–34; Gabathuler Decl. Ex. D p. 10.) But whereas Guetty *could* be closed at the proximal end, claim 1 of NovaPlast’s invention *must* be closed at the proximal end. At any rate, the application in its final form sufficed to satisfy the examiner, so the examiner’s approval does not impliedly rest on an exclusion of the single-first-fastener configuration. The issue here is patent construction, not patentability. Whether the examiner was right or wrong is not the issue; the point here is that this convoluted approval process does not imply that the claim means something other than what it says about single vs. multiple fasteners.

The day before the *Markman* hearing, Inplant and Proximate submitted two supplemental authorities: *Hakim v. Cannon Avent Grp., PLC*, 479 F.3d

---

<sup>10</sup> In fact, the prosecution history is devoid of an explanation for why the amendment was made.

<sup>11</sup> Recall, by the way, that *both* the original application and Guetty disclosed a plurality of fasteners.



1313 (Fed. Cir. 2007) and *Luv n' Care, Ltd. v. Koninklijke Philips Elec. N.V.*, 2013 WL 3471269 (E.D. Tex. July 9, 2013). (DE 68.) During oral argument I granted NovaPlast the opportunity to respond. (DE 71 p. 54.) NovaPlast objects to this submission as untimely (DE 70), but I will consider the supplemental authority and NovaPlast's response.

In *Hakim*, the applicant Hakim successfully persuaded the USPTO to allow patent claims by distinguishing his invention from prior art based on the use of a "slit" in the invention. *Id.* at 1316. After the USPTO allowed the claims, Hakim amended its claims in a continuation application to replace "slit" with the arguably broader term "opening." The continuation claims, with the substituted term "opening," were allowed by the examiner without any comment. *Id.* The Federal Circuit held that the term "opening" should have been limited to a "slit" because Hakim initially relied on the term "slit" to distinguish his invention from prior art and, in the continuation application, failed to rescind that disclaimer in a manner that would have fairly alerted the examiner to the necessity of revisiting the prior-art issue. *Id.* at 1317–18.<sup>12</sup>

This case is distinguishable from *Hakim*. *First*, the examiner here did not allow the patent claims on the basis that the claimed invention had a plurality of first fasteners, whereas prior art did not. (See Gabathuler Decl. Ex. G p. 9.) Rather, the examiner initially rejected the claims, expressly noting that the prior art did disclose a plurality of first fasteners. (See Gabathuler Decl. Ex. H p. 3.) *Second*, NovaPlast's amendments occurred during the prosecution history and prior to the examiner's allowance of the claims—not, as in *Hakim*, in a continuation application that occasioned no separate analysis. *Third*, in response to NovaPlast's amendments, the examiner issued a notice of allowability with a statement of reasons. (Baton Resp. Decl. Ex. 3.) Of note, the examiner discussed the amended claims in view of Preissman and recognized

---

<sup>12</sup> *Luv N' Care* involved a subsequent suit brought by the same patent holder regarding the same patent at issue in *Hakim*. *Luv N' Care* is relevant in that it relies heavily on *Hakim*, but it otherwise does not add much to the discussion. I will therefore focus on *Hakim*'s application to this case.



that, unlike Preissman, the amended claims required “a first fastener” and “a second fastener.” (*Id.*)

This is not the type of case the *Hakim* Court was concerned about, where a patentee “state[s] during prosecution that the claims do not cover a particular device and then change[s] position and later sue[s] a party who makes that same device for infringement.” *See Hakim*, 479 F.3d at 1318 (quoting *Springs Window Fashions LP v. Novo Indus L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003)). The prosecution history demonstrates that NovaPlast revised its claims during prosecution to encompass, *inter alia*, “at least one” first fastener, and that its claims were considered, discussed, and allowed by the examiner in their amended form.

Therefore, I conclude that NovaPlast did not abandon or disavow the plain and ordinary meaning of “at least one first fastener” by virtue of the positions it took during the prosecution history.<sup>13</sup>

---

<sup>13</sup> In the alternative, Inplant and Proximate argue that plaintiff’s construction lacks a sufficient written description and therefore renders claim 1 invalid under 35 U.S.C. § 112 and violates the new matter prohibition of 35 U.S.C. § 132. (*Id.* pp. 27–33.) These, I find, are not properly subjects for a *Markman* patent construction hearing.

Compliance with the written description requirement and the addition of new matter to a patent application are questions of fact. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010); *Commonwealth Sci. & Indus. Rsch. Organisation v. Buffalo Tech. (USA), Inc.*, 542 F.3d 1363, 1380 (Fed. Cir. 2008). “A patent is presumed to be valid, and this presumption can be overcome only by facts supported by clear and convincing evidence to the contrary.” *Enzo Biochem v. Gem Pride, Inc.*, 323 F.3d 956, 962 (Fed. Cir. 2002) (internal citation omitted); *see Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988).

At this stage, it would be inappropriate to determine whether the claims in the ’213 Patent are invalid for failure to comply with the written description requirement or for adding new matter to the application, because neither issue has yet been properly presented to the Court. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1327 (Fed. Cir. 2005) (“[W]e have certainly not endorsed a regime in which validity analysis is a regular component of claim construction.”). The claim construction here is made without prejudice to defendants’ ability to challenge the validity of the patent in due course.

For all of the foregoing reasons, I find that defendants' arguments cannot prevail. I adhere to the plain-language interpretation, *i.e.*, that the phrase "at least one first fastener" in claim 1 means "one or more than one first fastener(s)".

**B. and C. Claim 5 "each of the at least one first fastener" and "the first fasteners"**

The parties presented their dispute regarding this language from claim 5 in chart form as follows:

<b>Term</b>	<b>Plaintiff's Construction</b>	<b>Defendants' Construction</b>
"each of the at least one first fastener" ( <i>'213 Patent</i> , cl. 5)	No construction is necessary such that the plain and ordinary would apply, <i>e.g.</i> , every one of the first fasteners.	Each of the more than one first fasteners.
"the first fasteners" ( <i>'213 Patent</i> , cl. 5)	No construction is necessary such that the plain and ordinary would apply, <i>e.g.</i> , the one or more first fasteners.	The more than one first fasteners.

In the briefing, the parties at times shift ground, and at times fail to engage with each others' arguments. In the end, however, I conclude that claim 5 requires that there be a plurality of first fasteners.

The two relevant phrases, italicized for emphasis, occur within a single sentence in claim 5:

5. The delivery system of claim 1, *each of the at least one first fastener* further comprising a channel, the second fastener defining a shoulder, the shoulder adapted to be received within and secured with the channel of at least one of *the first fasteners*.

(Baton Decl. Ex. 1, col. 8:42–46 (emphasis added).)

I start with the first half of the quoted sentence from claim 5. Inplant and Proximate contend that the term "each of the at least one first fastener" signifies the presence of more than one fastener. (Def. Br. p. 37.) As previously

discussed, the plain and ordinary meaning of “at least one” encompasses both one and more than one; it does not exclude a single-fastener embodiment. See, e.g., *Rhine*, 183 F.3d at 1346. It is also true, however, that “each” or “each of” is a particular kind of determiner, presumptively used “to refer to the individual things or persons in a group of two or more.” Cambridge Dictionary, English Grammar Today, <https://dictionary.cambridge.org/us/grammar/british-grammar/each>; see also *Alcohol Monitoring Sys., Inc. v. Actsoft, Inc.*, 414 F. App’x 294, 299–300 (Fed. Cir. 2011). NovaPlast has overcome that presumption by adopting the awkward but clear singular noun “fastener”, not the plural “fasteners,” to expand the class from which “each” fastener is chosen. If *only* the plural fastener option was intended, the natural and grammatical drafting choice would be to simply use the plural noun, i.e., to specify “each of the first fasteners”. A contrary intent is suggested by the drafter’s deliberate choice of an unnatural singular noun.<sup>14</sup> While less than crystal clear, the sense seems to be that there can be any positive non-zero number of fasteners, and that, regardless of their number, each fastener comprises a channel. And indeed the focus of this clause is the nature, not the number, of fasteners. There is no clear exclusion of a single-fastener embodiment.

Things become more problematic, however, in the second half of the quoted sentence from claim 5, containing the phrase “at least one of the first fasteners.” Inplant and Proximate contend that the term must refer to two or

---

<sup>14</sup> The lack of an optional singular/plural construction again manifests itself. See n.8, *supra*. We do not say, for example, that “each of the jar” contains jelly beans, or “each of the cat” is black. NovaPlast was perhaps painted into a corner by its prior decision to globally substitute the broader “at least one” for “a plurality of,” the latter of which would always be paired with a plural noun, while the former would not.

So it is not entirely clear that NovaPlast chose the best mode of expression here, but the test is one of sufficient clarity, not room-for-improvement. Ironically, NovaPlast’s suggested construction—“every one of the first *fasteners*”—does not wholly escape the optional singular/plural trap. It would not be idiomatic to say “Only one person attended, but every one of them wore a blue shirt.” The meaning, however, would be clear enough.

more first fasteners, to the exclusion of a single-fastener embodiment, because on its face it is grammatically plural. (Def. Br. p. 36.) “In accordance with common English usage, we presume a plural term refers to two or more items.” *Apple Inc. v. MPH Techs. Oy*, 28 F.4th 254, 261–62 (Fed. Cir. 2022) (citing *Leggett & Platt, Inc. v. Hickory Springs Mfg. Co.*, 285 F.3d 1353, 1357 (Fed. Cir. 2002) (“[T]he claim recites ‘support wires’ in the plural, thus requiring more than one welded ‘support wire.’”)).

The plural interpretation also makes sense in context. “First fasteners” occurs within the phrase “at least one *of the* first fasteners,” which indicates that there are plural (i.e. two or more) fasteners, any of which could be selected to secure the corresponding shoulder. *See Apple Inc.*, 28 F.4th at 261–62; *SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 983 F.3d 1367, 1377 (Fed. Cir. 2021) (recognizing that the phrase “at least one of” requires one or more of each item in a conjunctive list).

That interpretation is reinforced by a comparison of the two claim 5 phrases being construed here. The first, discussed above, is “each of the at least one first fastener”; the second, discussed here, is “at least one of the first fasteners.” “At least one” is being used differently in these two phrases. The first phrase, as discussed, enumerates the *class* of first fasteners, and includes the case of one first fastener. The second, however, picks out “at least one” fastener *from* a class consisting “of the first fasteners” (plural). The entire premise of the second phrase is the existence of a plurality of first fasteners.

A party may overcome the presumption that “plural means plural” when the broader context shows that an alternative meaning was meant, such as where the term is used merely to “achieve grammatical consistency” with another term or generically to describe a function. *Apple Inc.*, 28 F.4th at 261–62. *See also In re Omeprazole Patent Litigation*, 84 F. App’x 76, 80 (Fed. Cir. 2003) (“one or more layers of materials” was meant to achieve grammatical consistency with “layers” and did not require multiple or diverse materials). No such demonstration is made here.

I conclude that the phrase “the first fasteners” in the second half of the claim 5 sentence is plural; it requires two or more fasteners. The term “at least one of the first fasteners” means “at least one of the more than one first fasteners.”

So the first half of the claim 5 sentence would not rule out a single-fastener embodiment, but the second half would. Harmonizing and construing the terms together, I must find that the second term narrows the first. Each fastener, however many there are, comprises a channel. But the corresponding shoulder is secured by a fastener that is one of a plurality of fasteners.<sup>15</sup>

**D. Claim 1 “based on the engagement of the second fastener with the at least one first fastener”**

The parties have formulated their dispute in chart form as follows:

<b>Term</b>	<b>Plaintiff's Construction</b>	<b>Defendants' Construction</b>
“based on the engagement of the second fastener with the at least one first fastener”  (’213 Patent, cl. 1)	No construction is necessary such that the plain and ordinary would apply, e.g., as a result of connection of a first fastener and a second fastener.	The mating engagement of the at least one first fastener, among the more than one first fasteners, with the second fastener performs the function of defining the size of the distal opening and forming the distal opening.

In claim 1, the disputed term “based on the engagement of the second fastener with the at least one first fastener” appears as follows:

the second fastener adapted to matingly engage with the at least [sic] first fastener and to close the longitudinal opening, whereby a predetermined size distal opening is formed *based on the engagement of the second fastener with the at least one first fastener*, the distal opening sized to allow the prosthetic implant to be urged therethrough.

<sup>15</sup> The upshot, presumably, is that claim 5 claims adjustable embodiments.

(Baton Decl. Ex. 1, col. 8:28–33 (emphasis added).) According to Inplant and Proximate, when the disputed claim term is considered in context, it should be construed as follows: “The mating engagement of the at least one first fastener, among the more than one first fasteners, with the second fastener performs the function of defining the size of the distal opening and forming the distal opening.” (Def. Br. p. 13.)

In order to accept defendants’ interpretation, the court would have to find in their favor on two related questions: (1) whether claim 1 requires a plurality of first fasteners and (2) whether an essential component of the invention is the ability to adjust the size of the distal opening.<sup>16</sup>

I have already determined that in claim 1, a plurality of first fasteners is not an exclusive requirement, because a single first fastener is also included.<sup>17</sup> I will therefore focus on the distinct but related second question: whether an essential element of claim 1 is to allow the user to adjust the size of the distal opening by selecting one or another of multiple first fasteners. (I will refer to this as a configurable or adjustable option.)

NovaPlast contends that claim 1 indeed includes multiple-first-fastener embodiments, which are configurable by the user, but also includes the single-first-fastener embodiment, which is not adjustable by the user. (Pl. Resp. pp. 7, 13.)<sup>18</sup>

---

<sup>16</sup> At oral argument, Inplant and Proximate acknowledged that central to their interpretation of claim 1 is that all embodiments permit the user to adjust the distal opening. See Tr. 34:22–35:4 (arguing that “a nonadjustable opening has been disclaimed”); Tr. 26:8–23 (“[Defendants]: Right. Well, actually, the engagement of the fasteners and the configuration of fasteners needs to provide the functionality of being able to adjust the size. [The Court]: Right. So it’s the adjustability of it that you’re talking about. [Defendant]: Exactly.”).

<sup>17</sup> See Section III.A., *supra*. As already noted, that requirement could be further narrowed in a dependent claim, such as claim 2 or claim 5, so as to include only multiple-fastener configurations. See n.18, *infra*; Section III.C, *supra*

<sup>18</sup> Here, NovaPlast contrasts claim 2, which is explicitly limited to a plurality of first fasteners. (Pl. Resp. pp. 7–8.) Claim 2 reads: “The delivery system of claim 1, wherein a plurality of first fasteners is formed on the elongated member adjacent the first longitudinal edge.” (Baton Decl. Ex. 1, col. 8:33–36.) NovaPlast adds that, were

To construe this claim I must endeavor to give the claim terms their “ordinary and customary meaning” in light of the words chosen, including consideration of the specification, which, if plain language does not settle the issue, “is the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315.

Once again, the plain language of the disputed phrase presents a formidable challenge to Inplant and Proximate. The “engagement of the second fastener with the *at least one* first fastener” clearly sets forth that there may be one first fastener, or more than one. See Section III.A., *supra*. In favor of a contrary interpretation, Inplant and Proximate offer four arguments, none of them ultimately convincing.

*First*, Inplant and Proximate stress that the contested phrase must be interpreted in the context of the surrounding words “predetermined size opening” and “sized.” Thus the phrase, in context, is “whereby a *predetermined size distal opening* is formed *based on the engagement of the second fastener with the at least one first fastener*, the distal opening *sized* to allow the prosthetic implant to be urged therethrough.” (Baton Decl. Ex. 1, col. 8:29–33 (emphasis added).)

The phrase “predetermined size opening” does not undermine NovaPlast’s position that claim 1 encompasses both (nonadjustable) single-first-fastener and (adjustable) multiple-first-fastener embodiments. Any engagement of the first fastener (whether single, or one of many) with the second fastener would necessarily create *some* size of distal opening. And presumably even a nonadjustable, single-first-fastener device could be *constructed* in alternative versions so as to have any one of a variety of distal openings, at the manufacturer’s option. It is not inherent in the ordinary and customary meaning of this phrase that *all* embodiments of the invention be

---

this claim not limited to multiple fasteners, it would duplicate claim 1 and therefore violate the claim differentiation doctrine. (Pl. Resp. pp. 7–8.)



adjustable *ad hoc* by the user—or, for that matter, that *none* of the embodiments be adjustable.

Defendants next point to the word “sized” and argue that claim 1 requires the capacity for “sizing,” in the sense of “adjusting,” the distal opening, which would imply multiple first fasteners. The shift is somewhat subtle, but the term in the claim is not “sizing” but “sized.” And the word “sized,” says NovaPlast, does not refer to the process of adjustment by the user; rather it simply means that the opening must be *of a size* sufficient to allow the prosthetic implant to be urged through. Consequently, it is not inconsistent with a single first fastener embodiment. (Pl. Resp. pp. 11–12.) I agree that “sized,” read in context, is not an active verb invoking the process of adjusting the opening. Rather, it is a modifier describing the distal opening as being *of a size* sufficient “to allow the prosthetic implant to be urged therethrough.”

*Second*, Inplant and Proximate assert that NovaPlast impliedly disavowed any device which lacks the adjustability feature by describing the “present invention” as one that possesses the adjustability feature. (Def. Br. p. 15.) “[A]n inventor may disavow claims lacking a particular feature when the specification describes ‘the present invention’ as having that feature.” *Poly-Am., L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016) (citing *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016)). In *Poly-America*, the specification for a trash bag invention stated that “one of the characteristics *of the present invention* is a reduction in upper width . . . resulting from the extended short seals.” *Id.* (emphasis in original). The court deemed this a clear statement that the claimed invention was limited to a trash bag with “extended short seals.” *Id.* at 1132, 1136–37.

According to Inplant and Proximate, the “present invention” is described as one which allows a user to select from multiple fasteners in order to create a desired size distal opening. (Def. Br. pp. 14–15.) In that connection, Inplant and Proximate cite this passage:

The *present invention* is directed to a delivery system for inserting a prosthetic implant through a surgical opening. *In some*



*embodiments*, the system comprises a flexible sheet of material defining a first side portion and a second side portion. Formed with either the first side portion or the second side portion, or both of the first and the second side portions are a plurality of fasteners. The fasteners are adapted to secure the first side portion with the second side portion to form an elongated hollow form that defines a distal opening. *In that there are a plurality of fasteners, a surgeon can select desired fasteners so that a desired size of the distal opening is determined by way of the particular fasteners that are used.* For example, fasteners towards the edges of the first and second side portions will, when the first and second side portions are secured with one another, define a relatively large distal opening. By contrast, fasteners spaced from the edge of the first or second side portions will, when the first and second side portions are secured with one another, define a smaller distal opening.

(Baton Decl. Ex. 1, col. 2:18–36 (emphasis added).)

This language falls far short of any explicit limitation of the “present invention” to adjustable embodiments. The actual phrase “present invention” is described only as being “directed to a delivery system for inserting a prosthetic implant through a surgical opening,” without specifying a fixed or adjustable option. The remainder of the quoted passage describes some embodiments of the invention. To be sure, those discussed embodiments are all adjustable ones, which allow the user to select the size of the distal opening. However, those descriptions of the embodiments are not clearly and unequivocally phrased so as to limit the definition of the “present invention” as a whole. That would require a clear statement that “all embodiments of the present invention” include the ability to select the size of the distal opening. *See Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016) (“We have found disavowal or disclaimer based on clear and unmistakable statements by the patentee that limit the claims, such as ‘the present invention includes . . .’ or ‘the present invention is . . .’ or ‘all embodiments of the present invention are. . . .’”); *Poly-Am., L.P.*, 839 F.3d at 1136. Without such a clear and unequivocal statement, I cannot find that Novaplast disavowed embodiments of

the invention that do not allow a user to select from multiple fasteners in order to create a desired size distal opening.

*Third*, Inplant and Proximate assert that NovaPlast distinguished its invention as an improvement over the “Keller Funnel”<sup>19</sup> implant delivery device, which permitted the user to select the size of the distal opening by trimming the distal end of the sleeve.<sup>20</sup> (Def. Br. p. 8.) In doing so, Inplant and Proximate say that NovaPlast characterized its invention as using the engagement of fasteners to size the distal opening in order to solve problems associated with trimming the distal opening. (*Id.*)

“[A]n inventor may disavow claims lacking a particular feature when the specification distinguishes or disparages prior art based on the absence of that feature.” Poly-Am., L.P., 839 F.3d at 1136 (citing *Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513–14 (Fed. Cir. 2015); *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1317 (Fed. Cir. 2015)). Here, Inplant and Proximate rely on the following passage:

While the flexible funnel [(the Keller Funnel)] has provided some advantages, the present invention addresses certain shortcomings to the funnel. Because adjustment of the opening through which the implant is squeezed is done by way of cutting a portion of the end of the sleeve, an error in sizing may result in having to discard the funnel and trim a new one, which can add to the cost of the procedure. Another problem that has been encountered with the funnel results when the force applied to the outside of the funnel to squeeze the implant sufficiently actually damages the implant. In addition to traumatizing the surgical site,

---

<sup>19</sup> According to defendants: “Preissman was assigned to Keller Medical Inc., the makers of the ‘Keller Funnel’ implant delivery device. The ‘213 Patent’s background references and discusses U.S. Pat. No. 8,211,173 issued to Keller et al., which is also assigned to Keller Medical, Inc. and directed to the Keller Funnel device. Preissman discloses an implant delivery funnel having a similar configuration to U.S. Pat. No. 8,211,173. ‘213 Patent, 1:46-2:12.” (Def. Br. p. 8 n. 2.) Plaintiffs do not dispute this description. Because it does not affect the outcome, I will adopt defendants’ description of the Keller Funnel for purposes of defining that term in this Opinion.

<sup>20</sup> At oral argument, counsel appeared to agree with the Court that a homespun example of such a trimmable nozzle might be a caulking gun.

the damaged implant cannot be used, which again increases costs. Another problem that has been experienced results when the force required to transfer the implant through the end of the sleeve causes the sleeve itself to burst at a seam. In some instances, the sleeve may fail due to a tear or inadvertent cut at the end of the sleeve accidentally made when the sleeve is trimmed. Although not common, another issue that may occur stems from the open proximal end that receives the implant. Because of the substantial lubrication that is utilized to allow the implant to be transferred through the distal end, possible mishandling of the flannel may result in the implant sliding out of the proximal open end.

The present invention seeks to address these shortcomings and provide an improved device.

(Baton Decl. Ex. 1, col. 1:57–2:14.)

The above passage does not provide the necessary clear statement of disavowal. The specification says that the present invention seeks to address the shortcomings of the Keller Funnel and provide an improved device, but it does not specify how. It may be assumed *arguendo* that the ability to adjust the distal opening using fasteners instead of trimming the nozzle may be a superior feature of the *adjustable embodiments* of the NovaPlast invention. Even so, there is no clear and unequivocal statement or implication that *all* embodiments must possess that adjustability feature.

*Fourth*, Inplant and Proximate argue that during the prosecution process, NovaPlast distinguished the Preissman and DiPoto prior art in a way that disclaims the formation of different size distal openings using an engagement of fasteners. Disavowal may occur where “the specification [or prosecution history] make[] clear that the invention does not include a particular feature.” *Luminara Worldwide, LLC*, 814 F.3d at 1353 (alterations in original).

The examiner initially rejected claims 1 and 8 of the ’250 Application because, among other reasons, the claims were unpatentable over Preissman, particularly in view of DiPoto. (Gabathuler Decl. Ex. C pp. 6–8.) In response, NovaPlast asserted that the examiner should not have combined Preissman and DiPoto because “[a] person of ordinary skill would have had no reason to

modify Preissman with DiPoto's for a teaching of an adjustable distal opening." (Gabathuler Decl. Ex. G pp. 9–10.) According to NovaPlast, Preissman "already solves the issue of different size distal openings" and "[i]ncluding the expandable distal end of Di[P]oto would still require the implant to be passed through a passage with a smaller diameter than the distal end," which would not alleviate any problem with larger implants. (*Id.* p. 10.)

NovaPlast's arguments concerned the propriety of treating a combination of Preissman and DiPoto as prior art, given the particular features of those inventions. The quoted passage is not specific to any claims of the patented NovaPlast invention. Therefore, NovaPlast's comments comparing Preissman and DiPoto do not reach the clear and unequivocal level required for finding a disavowal.

\* \* \*

Thus, I conclude that "based on the engagement of the second fastener with the at least one first fastener" has a plain meaning, but, for clarity, means "based on the engagement of the second fastener with the one or more first fastener(s)."

**E. Claim 1 first fastener "formed on the elongated member"**

<b>Term</b>	<b>Plaintiff's Construction</b>	<b>Defendants' Construction</b>
"formed on the elongated member" (’213 Patent, cl. 1)	No construction is necessary such that the plain and ordinary would apply, e.g., made or positioned on the elongated member.	Integrally formed with the elongated member.

The last claim term identified by Inplant and Proximate involves not the number but the nature of the first fastener(s). The claim term "formed on the elongated member" occurs twice in claim 1:

the distal end including a first longitudinal edge and a second longitudinal edge, the first longitudinal edge and second longitudinal edge further defining the longitudinal opening, at least one first fastener *formed on the elongated member* adjacent

the first longitudinal edge, and a second fastener *formed on the elongated member* adjacent the second longitudinal edge

(Baton Decl. Ex. 1, col. 8:20–27 (emphasis added).)

The word “formed” ordinarily means that something is made. *Richmond v. Forever Gifts, Inc.*, No. 14-cv-0583, 2015 WL 3421370, at \*10 (N.D. Tex. May 27, 2015); Webster’s New Universal Unabridged Dictionary 720 (2d ed. 1983) (defining “form” as “to make, shape, mold, or fashion; to make as in some particular way”). Despite this plain and ordinary meaning, Inplant and Proximate argue that “formed on” has the further implication of “integrally formed with.” The Court would be open to, *e.g.*, evidence that “formed on” is a term of art, but defendants offer no such evidence. Rather, they offer arguments based on the specification and the prosecution history. I am unpersuaded by either.

First, Inplant and Proximate rely on this sentence found in the description of one embodiment of the invention: “Each of the first fasteners 20 is either integrally formed with the sheet 12 or may be fixed thereto.” (Def. Br. p. 38; Baton Decl. Ex. 1, col. 4:44–47.) According to defendants, a person of ordinary skill in the art would understand that NovaPlast was here drawing a distinction between “formed on” and “fixed thereto,” but claiming only “formed on,” thereby dedicating to the public “fixed thereto.” (Def. Br. p. 38.)

So assume *arguendo* with defendants that “integrally formed with” is distinct from “fixed thereto.” That does not imply that “formed on” is distinct from “fixed thereto” unless “formed on” is equivalent to “integrally formed with.” Defendants do not demonstrate that these two phrases are equivalent. Far from it. The word “integral” has its own meaning and ordinarily connotes that “the parts are integrated as one complete unit.” *Richmond*, 2015 WL 3421370, at \*10. So in this phrase, “integrally” rather than “formed” seems to be doing the critical work for Defendants. It follows that swapping in “integrally formed with” for the actual language of claim 1 would impermissibly narrow the term “formed on” by requiring that the fastener be “made as one complete unit with”

the longitudinal edge. *See id.* Because the terms have not been shown to be equivalent, swapping them is not a valid approach here.<sup>21</sup>

At any rate, the specification provides that the fasteners may take several forms, including forms where the fastener is “fixed thereto”:

The plurality of fasteners may also take several forms. For example, formed with the first side portion may be a connection channel, while the second side may have formed therewith connection zippers, tabs or hooks adapted to be received within the connection channel and be secured therewith. Alternatively, the first side portion may define tabs and the second side portion may define slots adapted to receive the tabs so as to be secured therein.

(Baton Decl. Ex. 1, col. 3:10-17.) Adopting defendants’ construction would actually *exclude* those affixed embodiments expressly described in the specification, allowing only those “integrally formed with” the longitudinal edge. Such an approach to claim construction is “rarely, if ever correct and would require highly persuasive evidentiary support.” *Kaufman v. Microsoft Corp.*, 34 F.4th 1360, 1372 (Fed. Cir. 2022). I find no such persuasive evidence in the record.

*Second*, Inplant and Proximate argue from the prosecution history that NovaPlast distinguished its invention from Guetty in such a way that it disavowed fasteners affixed to the longitudinal edge. (Def. Br. p. 39.) During the prosecution history, the examiner rejected claim 8 as anticipated by Guetty because, among other reasons, Guetty disclosed first fasteners in the form of loops and second fasteners in the form of receiving slots:

Guetty further discloses a plurality of first fastener 9 formed on the elongated member adjacent the first longitudinal edge (as seen in Figures 1 and 3 in the form of loops) and a second fastener 13 formed on the elongated member 2 adjacent the second

---

<sup>21</sup> Additionally, such a swap would bring ambiguity, not clarity, to claim 1. “Integrally formed” is a term which is often contested but has been recognized as not having a fixed definition. *See James Davidson Enterprises, LLC v. Bolt Star, LLC*, No. 21-cv-01091, 2023 WL 415103, at \*4 (E.D. Cal. Jan. 25, 2023) (internal citations omitted) (collecting cases).

longitudinal edge 8B (in the form of receiving slots as seen in Figures 1 and 3) to form a seal.

(Gabathuler Decl. Ex. C. p. 4.) In response, NovaPlast argued that the sheet in Guetty is secured by a string, which should not be considered a fastener that is “formed with” the second side portion, or even a fastener at all:

The examiner relies on string 13 as the second fastener. The claim, however, specifies that the second fastener is formed with the second side portion. String 13 does not teach such a feature.

The claimed first and second fasteners include opposing mating structures. This is expressly disclosed in the claims. It cannot fairly be stated that Guetty discloses first and second fasteners at all. Instead, Guetty merely discloses a string that is used to fasten two sides of a sheet together. Absent the string, the sides of the Guetty sheet could not be fastened to one another.

(Gabathuler Decl. Ex. G p. 7.) NovaPlast’s statements to the examiner do not contain any clear statement that “formed on” excludes all affixed fasteners or includes only those fasteners that are “integrally formed with” the longitudinal edge. *See GE Lighting Sols., LLC*, 750 F.3d at 1309 (requiring clear evidence of disavowal). At most, NovaPlast disavowed the use of a string as a fastener to close the longitudinal opening.

Thus, I conclude that “formed on the elongated member” does not require construction and the plain and ordinary meaning applies.

### **ORDER**

Accordingly, for the reasons expressed above,

IT IS this 26<sup>th</sup> day of July, 2023,

ORDERED as follows:

A. In claim 1, “at least one first fastener” means “one or more than one first fastener(s)”.

B. In claim 5, “each of the at least one first fastener” means “each of the one or more than one first fasteners”.

C. In claim 5, “the first fasteners” means “the more than one first fasteners”. Taking B and C together, claim 5 covers only multiple-fastener embodiments.

D. In claim 1, “based on the engagement of the second fastener with the at least one first fastener” means “based on the engagement of the second fastener with the one or more first fastener(s)”.

E. In claim 1, “formed on the elongated member” requires no further interpretation, but, for clarity, should be understood as not excluding an affixed fastener or fasteners.

Dated: July 26, 2023

/s/ Kevin McNulty

---

**Hon. Kevin McNulty**  
**United States District Judge**